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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,888	10/06/2003	Nader Najafi	IB-12	3813

27127 7590 01/27/2009

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EXAMINER
MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
01/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/679,888	NAJAFI ET AL.	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,8,9,17-21 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,8,9,17-21 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/08 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sensor package being configured to block a pulmonary artery of the patient and/or blocking the second pulmonary artery with the sensor package, as claimed in claim 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites “further comprises telecommunicating and/or telepowering said sensing device with a readout device that is not adapted to be implanted in the patient”. It is unclear whether the invention further comprises telecommunicating or telecommunicating with a readout device. For the purpose of this examination only and to further prosecution, the examiner is assuming that the limitation refers to "telecommunicating” as written and not “telecommunicating with a readout device”. In

any case, the applicants should amend the claim to clearly reflect their intended meaning.

Claim 31 recites "further comprising cell growth and encapsulation . . .". wherein the limitations appear to be apparatus or device limitations. However, claim 31 is directed to a method. It is therefore unclear whether a method or apparatus is being claimed. For the purpose of this examination only, the examiner is assuming a method is being claimed. However, it is further unclear how these limitations relate to the claimed method. For the purpose of this examination only, the examiner is further interpreting the limitation to mean that the method further comprises encapsulating the sensor package. In any case, the claim must be amended to clearly reflect the intended meaning.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 9, 17-21, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication No. 2002/0151816 to Rich et al. in view of US Patent No. 7,147,604 to Allen et al. and US Patent No. 4,869,263 to Segal et al. Regarding claim 30, Rich teaches a hermetic sensor package and a

method of delivering the package to monitor pulmonary artery pressure within a patient. The package has a diameter and is adapted to be implanted into a pulmonary artery. The package is further configured to block the artery. The package comprises at least one sensing, said sensing device comprising at least one pressure sensor (see entire document, especially figs. 4, 15, 16; paragraphs 49, 65, 68, 89 of Rich). The method comprises injecting the sensor package so as to deliver the package into a blood vessel (see entire document, especially paragraph 77 of Rich), wherein the blood vessel is sufficiently small to prevent further movement of the sensor package and to anchor the sensor package therein (see entire document, especially figs. 15, 16 of Rich). The blood vessel is blocked, at least in part, with the sensor package, and the sensor package is operated while the vessel remains blocked by the sensor package to chronically monitor pressure in the vessel (see entire document, especially figs. 15, 16; paragraphs 77, 78 of Rich), wherein the sensor may be used to monitor pulmonary artery pressure (see entire document, especially paragraph 89 of Rich). Rich lacks injecting the sensor package into a first pulmonary artery, wherein blood flow through the first artery delivers the sensor package into a second pulmonary artery with a smaller diameter than the first.

However, Allen teaches monitoring pulmonary artery pressure, wherein a sensor package is injected into a site with the patient's vasculature so as to become lodged into a minor pulmonary artery or pulmonary capillary (see entire document, especially col. 7, lines 39-48 of Allen). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to lodge the sensor of Rich in a pulmonary artery or

capillary, since Rich teaches being injected so as to measure pulmonary artery pressure, and Allen teaches a pulmonary artery or capillary as an appropriate position for an implantable pressure sensor for monitoring a pulmonary pressure sensor. Rich, as modified, still lacks injecting the sensor package into a first pulmonary artery, wherein blood flow through the first artery delivers the sensor package into the second pulmonary artery, wherein the second pulmonary artery has a smaller diameter than the first.

However, Segal teaches lodging a device in a second pulmonary artery, wherein the device is first injected into a first pulmonary artery 129, and the blood flow through the first pulmonary artery delivers the device into the second pulmonary artery 131 and the second pulmonary artery has a smaller diameter than the first (see entire document, especially fig. 11; col. 5, lines 45-53 of Segal). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Segal with that of Rich, as modified, since Rich, as modified, teaches delivering and lodging the sensor to a pulmonary artery, and Segal describes an appropriate method of delivering and lodging a device in a pulmonary artery.

Regarding claim 2, implantation of the sensor package is performed for diagnosis of hypertension, wherein clearly, if the pulmonary arterial pressure is being monitored, then the determination of hypertension based on such a pressure is of pulmonary hypertension (see entire document, especially paragraph 81 of Rich; col. 1, lines 15-64 of Allen).

Regarding claim 3, the pressure sensor is a capacitive sensor (see entire document, especially figs. 1, 3-5; paragraph 57 of Rich).

Regarding claim 9, telecommunicating is performed and/or the device is telepowered with a readout device not adapted to be implanted in the patient (see entire document, especially figs. 1, 12; paragraphs 49-51, 71 of Rich).

Regarding claim 17, the injection of the sensor package into the pulmonary artery or similar vessel is a surgical technique (see entire document, especially col. 3, lines 63-65; col. 7, lines 39-48 of Allen; col. 5, lines 42-66 of Segal).

Regarding claim 18, the injection of the sensor package is a minimally invasive outpatient technique (see entire document, especially col. 3, lines 63-65; col. 7, lines 39-48 of Allen; col. 5, lines 42-66 of Segal).

Regarding claim 19, a catheter delivery technique is used to inject the sensor package (see entire document, especially col. 3, lines 63-65; col. 6, line 31-col. 7, line 48 of Allen).

Regarding claim 20, the sensor package comprises an anchoring mechanism (see entire document, especially figs. 15, 16; paragraphs 77, 78 of Rich).

Regarding claim 21, the sensor package is anchored to the artery by the diameter of the sensor package (see entire document, especially figs. 15, 16; paragraphs 77, 78 of Rich), wherein the package includes spring cage 112 or spring arms 116.

Regarding claims 32 and 33, at least a portion of the sensor package is coated with at least one coating (see entire document, especially paragraph 73 of Rich), wherein the coating may be parylene, polymer, or titanium

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rich in view of Allen and Segal, as applied to claims 2, 3, 9, 17-21, 30, 32, and 33 above, and further in view of US Patent 6,252,548 to Ishikawa. Regarding claim 4, Rich, as modified, teaches using a capacitor for temporary power storage but lacks a battery. However, Ishikawa teaches an implantable device comprising a power storage unit, wherein the power storage unit may be a capacitor, battery, or combination thereof (see entire document, especially fig. 5; col. 6, lines 43-65 of Ishikawa). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a battery in place of or in addition to the capacitor in the method of Rich, as modified, as it would merely be the substitution of one known power storage unit for another.

Regarding claim 5, wireless means for recharging the battery are included (see entire document, especially fig. 5; col. 6, lines 43-65 of Ishikawa).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rich in view of Allen and Segal, as applied to claims 2, 3, 9, 17-21, 30, 32, and 33 above, and further in view of US Patent No. 56,409,674 to Brockway et al. Rich, as modified, discloses that the data analysis circuitry may be included (see entire document, especially paragraph 50 of Rich) but is silent as to the details of the data analysis.

Brockway further discloses that the determination of dP/dt is useful in monitoring the work load of the heart (see entire document, especially col. 1, line 38-col. 2, line 6 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention for the data analysis circuitry of Rich, as modified, to determine dP/dt, as disclosed in Brockway, since Rich, as modified, discloses performing data analysis and Brockway further describes analyzing the pressure signal to determine dP/dt, wherein dP/dt is useful in determining the work load of the heart, among other things.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Rich and Segal, as applied to claims 2, 3, 9, 17-21, 30, 32, and 33 above, and further in view of US Patent No. 5,662,712 to Pathak et al. Regarding claims 31 and 32, Rich, as modified, lacks cell growth and encapsulation of the sensor package to stabilize the senor package. However, Pathak discloses a device implanted in an artery, wherein cell growth and encapsulation of the device are encouraged to stabilize/anchor the device (see entire document, especially col. 6, lines 1-24 of Pathak). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include cell growth and encapsulation as shown in Pathak in the method of Rich, as modified, in order to further stabilize or anchor the sensor.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

While new grounds of rejection have been presented, the new grounds of rejection still rely upon the Segal reference. Applicants' comments as to the Segal reference are applicable to the new grounds of rejection, and, therefore, are addressed here. The applicants argue that Segal fails to deliver the sensor in a pulmonary artery. However, as set forth in the previous Office action and above, the Segal reference is relied upon to show how a device, and not necessarily a sensor, may be floated from a larger pulmonary artery 131 to a smaller pulmonary artery 129 so that it is lodged in the pulmonary artery. The position of the sensor of Segal is irrelevant because Allen already teaches positioning a sensor in a pulmonary vessel and the combination of references, not Segal, alone is relied upon to teach the overall method of floating a sensor from a larger pulmonary artery to a smaller one so that it becomes lodged in the smaller artery. The applicants' arguments as to Segal are, therefore, not persuasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735